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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,636	04/01/2004	Patrick T. Petruno	119204-007	1047

24573 7590 08/13/2009

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
08/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,636	PETRUNO ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,21-23,26 and 39-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,21-23,26 and 39-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 June 2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11, 12, 21-23, 26, 39-41, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby

(US 6,217,744) further in view of Holmes, II et al. (US 5,371,687) and May et al. (US 5,602,040).

Daniels et al. teach a test system comprising:

a test strip having:

a test stripe (anti-analyte 1 epitope B, Fig. 1; par. 218),

a control stripe (control line, Fig. 1; par. 218), and

a receiving zone (area under arrow pointing to test strip under sample is sample receiving zone, Fig. 1; sample pad, par. 219),

the test strip being capable of generating a response at the test strip and the control stripe subsequent to contact of a single liquid sample in the receiving zone (par. 219 and 220; one liquid sample is applied to the test strip, sample is either mixed with detection reagent prior to application to test strip and sample and detection reagent are applied together or detection reagent is embedded in the test strip and only the single liquid sample is applied to the test strip, par. 217-219), the test stripe containing a labeling substance that comprises first persistent fluorescent structures that emits light having a first frequency and second persistent fluorescent structures that emit light having a second frequency, wherein each of the first persistent fluorescent structures is attached to a substance that is capable of binding the first structure to a target analyte after a sample fluid containing the target analyte is applied to the receiving zone (each detection reagent is associated with a nanocrystal having a distinct emission peak and nanocrystal is a persistent fluorescent structure, par. 207;

capture and control reagents bind the first and second structures and are present in a chromatographic medium therefore the first and second nanocrystal structures are present in a medium, par. 201; emission peak of nanocrystal incorporated into control is distinct from that exhibited by nanocrystals of the first detection reagent therefore first and second nanocrystals emit at different frequencies, par. 198);

a light source positioned to illuminate a target area and a control area on the medium within the single use module, the target area encompassing the test stripe and the control area encompassing the control stripe (par. 213);

a first photodetector positioned to measure light of the first frequency from the target area (multiple detectors for each light emission frequency, par. 214); and

a second photodetector positioned to measure light of the second frequency from the control area, wherein a signal from the second photodetector indicating an intensity above a threshold level indicates that the sample has passed through the target area (separate detector for each detection region with a different emission frequency, par. 214; control region has a different emission frequency than detection region, par. 198; detection of nanocrystals in the control region occurs in the presence or absence of analyte and therefore indicates that the sample has passed through the medium, par. 242).

Daniels et al. fail to teach the first and second photodetectors and medium contained in a single-use module, a cap arranged to cover an opening in the single use module to isolate the single liquid sample and a terminal for receiving electrical power

from a source external to the single-use module, the terminal comprising conductors along an external surface of the single use module and part of an interface that is received in a receptacle of a reusable module.

Crosby teaches a photodetector and medium necessary for optical detection contained in a single use module (optical components and porous membrane are part of the disposable device, optical components comprise the photodetector, col. 5, lines 64-col. 6, line 13) and inserted into a reusable module for communication of test signals between the single-use module and reusable module (communication between disposable analysis device and information gather and storage system, disposable device is single use and information gathering system is reusable, col. 6, lines 57-67; col. 7, lines 37-45) and the single use module comprising an external terminal receiving electrical power for the electronics in the device, including light sources and photodetectors (capacitor is external terminal that receives electrical power, col. 8, lines 28-40; electronics include light source and photodetectors, col. 6, lines 46-50), wherein the reusable module has a receptacle into which the external terminal of the single use module can be inserted to provide electrical power and communicates test signals between single use module and reusable module (device is brought in proximity to console, col. 8, lines 28-40; device may alternatively be placed into the console for transfer of data and to provide electrical power, col. 7, lines 6-10), in order to provide a self powered device that resists corrosion and degradation. Crosby teaches that while not preferable, it is possible to directly electrically connect the device to a reader for power supply and information gathering (col. 6, lines 57-67) and Crosby also teaches

that power to the diagnostic device may be provided inductively, but not conductively, by an electrical power source external to the single-use module (col. 8, lines 28-40). All disclosures of non-preferred embodiments must be considered. *In re Nehrenberg*, 126 PQ 383. *In re Boe*, 148 PQ 507. *In re Mill and Palmer*, 176 PQ 196 (CCPA 1972) . *In re Simon*, 174 PQ 114. *In re Lamberti et al.*, 192 PQ 278 (CCPA 1976).

Holmes, II et al. teach a module that has a terminal for insertion of a single use module (housing mated to data processing module, col. 3, lines 6-10), that has a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source external to the single-use module and configured to be pluggably inserted into the receptacle of the reusable module for communicating test result signals (housing is mated to data processing module and conductors connect the module to an external power supply, col. 3, lines 19-36), in order to provide glucose measurements in a device that can interface with a printer, store larger numbers of patient glucose numbers, perform various calculations and interface a number of different types of glucose measurements to a computer.

May et al. teach a test strip in a single use module comprising a cap arranged to cover an opening in the single use module to isolate the single liquid sample (cap 503 covers opening in test strip to isolate the sample, 506, Fig. 8; col. 12, lines 14-19), in order to cover the porous member.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., the photodetectors and medium necessary for optical detection contained in a single use

module that can be inserted into a reusable module for communication of test signals as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability. Although Crosby does not specifically teach two photodetectors, it would have been obvious to include all photodetectors of Daniels et al. necessary for detection in the single use device taught by Crosby. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Daniels et al. in view of Crosby, a terminal located on an external surface of the single-use module for conductively receiving electrical power from a source as taught by Holmes, II et al., in order to provide sample measurements over an extended period of time longer than the battery life of a device. Although Holmes, II et al. do not specifically teach the module having a terminal being single use, such a limitation is drawn to intended use of the module and claim 11 does not recite any specific structural limitations that render the module single-use. Since the module of Holmes, II et al. teach the structural limitations for a single use module as recited in claim 11, which is the module having a terminal on the external surface of a module which can be inserted into a reusable receptacle for providing electrical power and communicating test signals, and the module of can be removed from the reusable module, the module having a terminal as taught by Holmes, II et al. is capable of being disposed after a single use. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to include on the test strip device of Daniels et al. in view of Crosby

et al. further in view of Holmes, II et al., a cap as taught by May et al., in order to prevent contamination of the sample during testing.

Daniels et al. in view of Crosby et al. further in view of Holmes, II et al. and May et al. do not specifically teach the application of the single liquid sample to the receiving zone of the test strip excluding the use of the light source, the first photodetector and the second photodetector disposed within the single use module from being used to analyze an additional liquid sample different from the single liquid sample. However, such a limitation is drawn to intended use of the test strip and does not provide any specific structural limitations to the test strip and therefore the prior art must only be capable of performing the intended use. Since the combination of prior art references teach the required structural limitations of claim 1, the prior art is capable of performing the recited intended use. Furthermore, since Daniels et al. teach detection of multiple analyte in a *single* sample, it is clear the application of liquid to the test strip of Daniels et al. in a single housing as taught by Crosby et al. excludes the use of the test strip and the light source and first and second photodetectors with additional liquid samples.

With respect to claims 12, 21 and 22, Daniels et al. fail to teach a reusable module with a user interface indicating an electrical test result.

Crosby teaches the reusable module implementing a user interface capable of indicating a test result on a display (console is the information gathering and storage system and has a display screen to display results from the disposable device, col. 7, lines 37-50) and the test signals are electrical signals (col. 7, lines 14-25).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the test system of Daniels et al., a user interface that displays electrical test signals on a display as taught by Crosby, in order to provide small, point of care diagnostic tests that are small in size and produces a fast quantitative or qualitative result with increased reliability.

With respect to claim 23, Daniels et al. teach the first and second persistent fluorescent structures comprising quantum dots (par. 198 and 79).

Regarding claim 26, Daniels et al. teach the medium comprising a lateral-flow strip for performing a binding assay (par. 200-201) and the target area containing an immobilized substance that binds to and holds the complex including one of the first persistent structures and the target analyte (par. 200-201; capture reagent binds to the detection complex, par. 189; detection complex comprises analyte and nanocrystal, par. 137-139; capture reagent is in a capture region, par. 115).

With respect to claims 39 and 40, Daniels et al. teach the second persistent structures bind to the control strip (control ligands are in a control region, par. 115; control ligands bind to second persistent structures that have an emission frequency different from that in the capture region, par. 198). Daniels et al. also teach a first and second color filter corresponding to the first and second photodetector that transmit the first and second frequencies, respectively (multiple detectors are present, one for each region, and each has a bandpass filter for detecting a narrow wavelength range corresponding to the nanocrystal emission wavelength in the capture and control regions, par. 214).

With respect to claim 41, Daniels et al. teach the control stripe containing an immobilized substance that binds and retains the labeling substance (par. 26 and 38).

Regarding claims 43 and 45, Daniels et al. teach the optical system comprising a chromatic prism (prism spectrally resolves colors, par. 172) or diffractive grating (par. 171 and 172).

2. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2002/0004246) in view of Crosby (US 6,217,744) further in view of Holmes, II et al. (US 5,371,687) and May et al. (US 5,602,040), as applied to claim 11, further in view of Cliche et al. (US 2003/0174743).

Daniels et al. in view of Crosby further in view of Holmes, II et al. and May et al. teach an optical system comprising a diffractive grating between the light source and the photodetectors (par. 171), but fail to teach an optical system comprising a thin-film filter.

Cliche et al. teach either a diffractive grating, thin-film filter (par. 69) or lenses (par. 89), in order to filter large optical bandwidths.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the system of Daniels et al. in view of Crosby further in view of Holmes, II et al. and May et al., an optical system comprising a thin-film filter as taught by Cliche et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent optical modification technique and since the same light signal would have been obtained. The use of alternative and functionally equivalent techniques would have

been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

3. Applicant's arguments with respect to claims 11, 12, 21-23, 26 and 39-46 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the new limitations of a cap arranged to cover an opening in the single use module, which is taught by May et al. and a terminal for receiving electrical power from an external source which is taught by Holmes, II et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Patent Examiner, Art Unit 1641